

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

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| Applicant's or agent's file reference 1282-P03335WO00 | FOR FURTHER ACTION | | See Form PCT/IPEA/416 |
| International application No. PCT/US04/39533 | International filing date (day/month/year) 24 November 2004 (24.11.2004) | Priority date (day/month/year) 24 November 2003 (24.11.2003) | |
| International Patent Classification (IPC) or national classification and IPC IPC: A61K 31/16(2006.01),31/38(2006.01),31/40(2006.01),31/44(2006.01),31/435(2006.01) USPC: 514/277,336,340,342,346,422,438,447,613 | | | |
| Applicant VIROPHARMA INCORPORATED | | | |
| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of ___ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> | | | |
| <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p> | | | |
| Date of submission of the demand 24 June 2005 (24.06.2005) | | Date of completion of this report 11 April 2006 (11.04.2006) | |
| Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201 | | Authorized officer <i>Kevin E. Weddington</i> Kevin E. Weddington Telephone No. (571) 272.1600 | |

Form PCT/IPEA/409 (cover sheet)(April 2005)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US04/39533

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

- ☒ the international application in the language in which it was filed.
- ☐ a translation of the international application into English, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4(a))
- ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

- ☒ the international application as originally filed/furnished
- ☒ the description:
- pages 1-40 as originally filed/furnished
- pages* NONE received by this Authority on _____
- pages* NONE received by this Authority on _____
- ☒ the claims:
- pages 41-54 as originally filed/furnished
- pages* NONE as amended (together with any statement) under Article 19
- pages* NONE received by this Authority on _____
- pages* NONE received by this Authority on _____
- ☒ the drawings:
- pages 1/3-3G/3 as originally filed/furnished
- pages* NONE received by this Authority on _____
- pages* NONE received by this Authority on _____

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE
- ☒ the claims, Nos. NONE
- ☒ the drawings, sheets/figs NONE
- ☒ the sequence listing (*specify*): NONE
- ☒ any table(s) related to the sequence listing (*specify*): NONE

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

** If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US04/39533**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | |
|-------------------------------|--------------------|-----|
| Novelty (N) | Claims <u>NONE</u> | YES |
| | Claims <u>1-32</u> | NO |
| Inventive Step (IS) | Claims <u>NONE</u> | YES |
| | Claims <u>1-32</u> | NO |
| Industrial Applicability (IA) | Claims <u>1-32</u> | YES |
| | Claims <u>NONE</u> | NO |

2. Citations and Explanations (Rule 70.7)

Claims 1-32 meet the criteria set out in PCT Article 33(4) as having industrial applicability in the pharmaceutical art.

Claims 1-32 lack novelty under PCT Article 33(2) as being anticipated by Arcamone et al. (4,738,980), Crute et al. (6,057,451), Crute et al. (6,288,091) and Axxima Pharmaceutical AG (WO 01/56553).

Each of the four cited references, individually teaches compounds having the core structure disclosed in claim 1 of the applicants having antiviral activity. Note in the Crute et al. (6,057,451) reference teaches methods for identifying compounds that modulate NS4B signal transduction.

Claims 1-32 lack an invention step under PCT Article 33(3) as being obvious over Arcamone et al. (4,738,980), Crute et al. (6,057,451), Crute et al. (6,288,091) and Axxima Pharmaceutical AG (WO 01/56553).

The four primary references were discussed above supra the instant compounds are well-known antiviral agents.

The instant invention differs from the cited references in that the cited references do not teach the instant compounds are used to treat hepatitis C. However, one skilled in the art would have assumed that the antiviral agents of the cited references would inherently treat any viral infections such as hepatitis C in the absence of evidence to the contrary.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 1-15 are objected to as lacking clarity under PCT Rule 66.2(a)(v) because of the claims not fully supported by the description. The description does not disclose the claimed invention in a manner sufficiently clear and complete for the claimed invention to be carried out by a person skilled in the art because:

Applicants' description does not contain any test results or experimental data showing the instant compounds with the core structure of claim 1 will, in fact, prevent (prophylaxis) viral infections, including hepatitis C, in a living host not presently at risk of or predisposed to developing such an infection.